§ 114.14 Extension of expiration date for a serial or subserial.

(a) Unless otherwise provided for in a filed Outline of Production for the product, the expiration date shall not be extended:

(1) If all fractions of the product are not evaluated for potency by tests designated in the filed Outline of Production for such product in accordance with §113.4(b) of this subchapter.

(2) For any serial or portion of any serial which has left licensed premises:

Provided, That product which has been shipped from one licensed premises to another licensed premises shall be exempt from this requirement.

(3) For a serial or portion of a serial if the expiration date has been extended previously, unless otherwise authorized in accordance with §114.1.

(b) An extension of the expiration date may be granted by Animal and Plant Health Inspection Service if a request from the licensee is substantiated by valid test data which demonstrate that the potency of the product meets or exceeds the requirements for release. The new expiration date shall be calculated from the date the latest satisfactory potency test was initiated. The extension of the expiration date shall not exceed the maximum dating allowed in the filed Outline of Production.

(1) Serials are approved for redating under the condition that Animal and Plant Health Inspection Service may require the firm to retest the redated serial for potency during the extended dating period if the retested products are unsatisfactory. If so, the firm may be required to remove the unsatisfactory product from the market by the licensee.

(2) [Reserved]


§ 114.15 Disposal of unsatisfactory products and byproducts.

All biological products found to be unsatisfactory for marketing, all biological products which have become worthless subsequent to the expiration date, all refuse, other materials deemed unsatisfactory for production purposes, all carcasses (part or whole) of production or test animals, and any undesirable byproducts of manufacture shall be disposed of as may be required by the Administrator.


§ 114.16 Producing subsidiaries.

A serial or subserial of a biological product may be produced jointly by a licensee and one or more subsidiaries, or by two or more subsidiaries. The exact amount of each serial or subserial credited to each participating producer shall be determined at the time of labeling and packaging and shall be noted in the records for such serial or subserial.

[40 FR 46093, Oct. 6, 1975]

§ 114.17 Rebottling of biological products.

The Administrator may authorize the rebottling of a completed product in liquid form subject to the conditions prescribed in this section.

(a) All or part of a serial which has not left the licensed establishment may be aseptically returned to the mixing tank, thoroughly mixed, and rebottled in new final containers.

(1) Rebottling of a serial or subserial that has not left the licensed establishment may be authorized if the rebottled product is adequately identified by a serial number or subserial number, as the case may be.

[b]